

REMARKS

Reconsideration of the present application as amended is requested. In the present office action, claims 117, 118, 121, 125-129 and 204 were rejected under obviousness-type double patenting. Applicants will file an appropriate terminal disclaimer to overcome this rejection once the prior rejections have been addressed. Claims 117, 118, 121, 125-129, 201-204, 217 and 218 were rejected as anticipated by the patent to Brantigan (No. 5,192,327). Claims 117 and 201-203 were further rejected as anticipated by the patent to Samani (No. 5,645,599).

The anticipation rejection in view of the Brantigan patent is based on an erroneous reading of that reference. It is acknowledged that the Brantigan "plugs" can be formed into an expandable structure and that this structure is capable of maintaining two vertebral bodies apart in a distracted position. However, the Brantigan plugs cannot accomplish either function by insertion between the opposing tissue surfaces. Contrary to the assertion in the Office Action, there is absolutely nothing in Brantigan that discloses or suggests that the plugs can be "inserted one after another." It can first be noted that the proposed grounds for finding anticipation required modification of the Brantigan disclosure. Brantigan does not disclose "moving the insertion tool sideways instead of forward/backward." Nor does Brantigan disclose inserting the plugs one after the other into the space between vertebrae. Finally, Brantigan does not disclose positioning "the inserts atop one another by moving them sideways." Thus, at a minimum, the stated grounds for rejection legally sound more like obviousness than anticipation.

It makes no sense to propose modifying the Brantigan disclosure by "moving the insertion tool sideways." This suggestion in the Office Action apparently recognizes that the ridges prevent insertion of the plugs into an undistracted space and prevents insertion of one plug adjacent another plug, at least in the direction of insertion clearly specified in Brantigan and illustrated in FIG. 13 of that reference. In order to avoid a wholesale modification of the structure of the Brantigan plug, the fiction was created that the same insertion tool 73 and tool engagement hole 13 can be used if the tool is moved sideways. Of course, this suggested approach flies in the face of the procedure described in Brantigan in which the direction of insertion is along the axis of the tool 73. Moreover, this suggested approach would require a much larger surgical site since the assembled stack of plugs 12 would have to be introduced into the patient's body in one direction and then moved sideways in a perpendicular direction to enter the space between vertebrae.

Even if this extreme surgical procedure is medically acceptable, insertion of the Brantigan plugs in this direction would defeat the stated purpose of the ridges on the Brantigan plugs – namely, to resist expulsion. If the plugs are inserted sideways along the axis of the ridges, then the ridges are incapable of resisting expulsion of the plugs in this sideways direction of insertion. The only way that the ridges can function is to resist expulsion in the direction of insertion, which is clearly illustrated in FIG. 13 of Brantigan. Thus, it is clear that the suggested change to the procedure disclosed in Brantigan would entirely frustrate an important feature of that device.

In addition, there is no disclosure in Brantigan of consecutively inserting each plug. Brantigan only discloses creating the stack prior to insertion into the patient. See, col. 6, lines 59-68. Thus, the act of distracting the space occurs before the stack of Brantigan plugs is inserted, not during the insertion as required by Applicants' claims. Even in this regard, the Office Action lacks any explanation as to how individual plugs in Brantigan, sized as they are depicted in FIG. 12, can be somehow jammed between or beneath each other for consecutive individual receipt between the tissue surfaces, as recited in Applicants' claim 117. To further distinguish Applicants' invention over the plugs in Brantigan, claim 117 has been amended to indicate that the elements have an entry surface configured to facilitate entry of each element into the expandable structure between the tissue surfaces. There is no disclosure or suggestion in Brantigan of any such entry surface on the Brantigan plugs, nor would such a feature be contemplated by Brantigan since the plugs are intended to be assembled into stacks outside the patient.

With respect to claims 201-203, these claims do not simply claim "a length" as suggested. Instead, the claims call out that the elements have a length and a width. Although conventional interpretation of these terms would be that the length and width is of the entire wafer/element, Applicants have amended claims 201 and 202 to indicate that the length and width are of substantially the entire element. Of course, the length and width of the Brantigan plugs are identical so Brantigan cannot anticipate claims 201-203. Moreover, there is no suggestion in Brantigan to provide plugs having any different lengths or widths, especially since the plugs rely upon interdigitation between the ridges on the surfaces of the plugs.

Claims 117 and 201-203 were rejected as anticipated by Samani. However, this rejection is based on a fiction – that the purported stackable elements are "substantially similarly

configured", as defined in Applicants' claim 117. Incredibly, this rejection is premised on the statement that the parts of the Samani interspinal implant "are more alike than they are different." In making this rejection, the U-shaped body 5 has been defined as a top wafer (branch 5a) and a bottom wafer (branch 5b) and an additional wafer (cushion 15). While the two branches of the one-piece U-shaped body 15 may be "more alike than different", there is no conceivable way that the cushion 15 can be regarded as substantially the same configuration as the branches 5a, 5b. As seen in FIG. 1, the branches 5a, 5b are in the form of rectangular plates with brackets 6 projecting therefrom. On the other hand, the cushion 15 is a block of material that fits within the space of the U-shaped body 5. No matter how broadly the term "substantially" is defined, the construction applied in making the rejection virtually eliminates the requirement that the elements be "similarly configured". Of course, even the dictionary definition recited in the Office Action ("largely but not wholly that which is specified") is not so broad as to support the proposition that the cushion 15 is "substantially similarly configured" to the parts of the U-shaped body 5.

Moreover, there is no suggestion in Samani that insertion of the cushion within the U-shaped body 5 "expands" the structure or "distracts" the tissue surfaces. To the contrary, Samani, like Brantigan, requires that the adjacent vertebrae be separated prior to introduction of the cushion. See, col. 2, lines 53-58. Moreover, the cushion is operable to limit the movement of the branches 5a, 5b toward each other (col. 2, lines 60-65), so there is no suggestion that the cushion is capable of expanding the structure or distracting the tissue surfaces.

Finally, there is no disclosure or suggestion in Samani that multiple cushions 15 are inserted into a single U-shaped body 5, or that multiple U-shaped bodies 5 are inserted between opposing tissue surfaces. Since the cushion 15 is intended in Samani to limit movement of the branches toward each other, there is no reason to successively insert multiple cushions into the U-shaped body. The irregular shape of the U-shaped body 5 militates against placing two such bodies next to each other between adjacent spinous processes. The only use of more than one U-shaped body is depicted in FIG. 4 in which each body is situated between a different pair of spinous processes. In this figure, the two U-shaped bodies do not engage each other to form an expandable structure.

It is therefore believed that each of the pending claims is allowable over the art of record. Neither Brantigan nor Samani disclose every limitation in the claims. Moreover, any

modification to the device in either reference would be significant and well beyond what would be obvious to a person of ordinary skill in this art. Furthermore, modifications to the Brantigan plug to meet the limitations of Applicants' claims would eliminate an important feature of those plugs, namely the ability of the ridges to resist expulsion in the direction of insertion of the plugs.

Applicants have presented new dependent claims 219-225 directed to more specific features of the invention. For instance, claim 219 further defines the entry surface as being angled. Claims 220-224 add a restraining element to the expandable structure and plurality of elements that restrain relative movement in either or both the transverse direction and the given insertion direction. Claim 225 adds an outer member exteriorly of the plurality of elements. All of these new claims benefit from the patentability of the independent claim 117 and are also believed to be patentable over the cited art on their own merits.

Concurrent with this response Applicants have submitted an Information Disclosure Statement citing newly discovered U.S. Patent No. 5,836,948. The Commissioner is authorized to deduct the necessary fee for this supplemental IDS from Deposit Account 13-0014.

In view of the foregoing arguments and amendments, it is believed that all of the pending claims 117, 118, 121, 125-129, 201-204, 217, 218 and new claims 219-225 are allowable over the art of record. Action toward a Notice of Allowance is earnestly requested.

Respectfully Submitted,

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